

App. No. 10/520,330  
Office Action Dated November 15, 2005

### **REMARKS**

Reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1, 7 and 8 have been amended. Claim 1 has been amended to incorporate the limitation of the peritoneal equilibrium test (PET) being performed last of all the steps, and the blood test being performed immediately before the PET, or during the PET, which is supported for example by page 4, lines 26-29. Claims 7 and 8 have been amended editorially. Claim 2 has been canceled without prejudice or disclaimer. Claim 9 is a new independent method claim, and is supported by page 4, lines 26-29. No new matter has been added. Claims 1 and 3-9 are pending.

#### ***Claim rejections - 35 U.S.C. § 112***

Claims 2, 7 and 8 are rejected under 35 U.S.C. 112(a), second paragraph, as being indefinite for failing to claim the subject matter of the present invention. Claim 2 has been canceled. Claims 7 and 8 have been amended editorially, taking the issues noted in the rejection into account. Applicants submit that claims 7 and 8 are definite.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

#### ***Claim rejections - 35 U.S.C. § 103***

Claims 1-8 have been rejected under 35 U.S.C. 103(a) as obvious over Chen et al. (U.S. Patent No. 5,670,057) in view of Milner (U.S. Patent No. 6,077,836) and Kelton et al. (1978). Applicants respectfully traverse this rejection.

Claim 1 requires the steps of (1) analyzing a drain fluid while repeatedly performing fluid infusion and fluid drain of a predetermined amount of peritoneal dialysis fluid in alteration for peritoneal dialysis fluids having different osmotic pressures, (2) performing a PET, and (3) performing a blood test. Significantly, claim 1 further requires the PET to be

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performed last of all the steps and the blood test to be performed only once, either immediately before the PET or during the PET.

Chen fails to suggest performing the PET to be performed last of all the steps and the blood test only once either immediately before the PET or during the PET. Neither Milner nor Kelton rectify this deficiency. In fact, Milner discloses a method that includes taking more than one blood sample over a 24 hour period, thereby teaching away from the present invention (col. 23, lines 60-67 and col. 24, lines 1-4). Kelton fails to disclose any method that includes performing a PET. Thus, Milner and Kelton fail to suggest the method of the present invention, even in combination with Chen.

There are advantages enjoyed by performing the PET last of all the steps and the blood test only once either immediately before the PET or during the PET. For instance, in a conventional 24-hour test, when a blood sample is taken and the PET is performed at the start of testing, the patient is required to be admitted to the hospital. On the other hand, because the storage of drained dialysis fluid is possible at home, if the patient were to bring drained dialysis fluid samples to the hospital and have blood drawn after testing is finished, it would not be necessary for the patient to be admitted to the hospital. As such, all the tests can be performed on the same day, and thus, less constraint and burden is placed on the patient, as well as the medical staff.

The present invention is based on the finding that there is very little change in the blood solute concentration of chronic peritoneal dialysis patients during the conventional 24 hour test period. This finding is demonstrated, for example in Figs. 3-5. Here, 100 chronic peritoneal dialysis patients were tested using the conventional method for testing peritoneal function as shown in Fig. 1, in which blood samples were taken and drained dialysis fluid was

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stored over a 24 hour period to measure the concentration of monitored solutes in blood and drained fluid during testing. As shown in Figs. 3-5, there was very little change in the blood concentration of all of the monitored solutes, these being total protein, albumin, glucose, creatinine, urea, sodium, and chlorine, which are important for confirming the constancy of chronic peritoneal dialysis patients, between that at the start of testing and that after the 24 hour test period. Accordingly, blood samples taken at the end of the testing period can be used as a representative sample during the 24-hour period. As such, the method for testing peritoneal function is simplified without affecting the results.

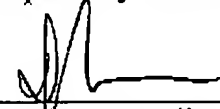
Claims 3-8 depend from claim 1. Claims 3-8 are patentable over Chen, Milner and Kelton for at least the same reasons as claim 1.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully Submitted,

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